



**Clinical  
Research  
Laboratories, Inc.**

**Final Report**

**Repeated Insult Patch Test**

**CLIENT:** React, Inc.  
3765 Kettle Court East  
Delafield, WI 53018

**ATTENTION:** Mr. Bruce Tavares

**TEST MATERIAL:** All Natural Cotton Powder - Unwashed  
Batch #2161

**CRL STUDY NUMBER:** CRL136502-1

**AUTHORIZED SIGNATURES:**

\_\_\_\_\_  
**Bruce E. Kanengiser, M.D.**  
President/Medical Director

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**Marilee Candino, R.N.**  
Director/Clinical Services

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**George J. Neumaier, M.D.**  
Diplomate American Board  
of Dermatology

\_\_\_\_\_  
**Michael J. Muscatiello, Ph.D.**  
Executive Vice President/C.O.O.

**REPORT DATE:** February 25, 2003



**Clinical  
Research  
Laboratories, Inc.**

**Good Clinical Practice  
Final Report Review Statement**

**Clinical Study Number:** CRL136502-1

**Start Date:** January 6, 2003

**Completion Date:** February 14, 2003

This clinical study report has been reviewed to assure that it correctly describes the method of testing and that the reported results accurately reflect the data obtained during the study.

\_\_\_\_\_  
Reviewer

\_\_\_\_\_  
Date



# Clinical Research Laboratories, Inc.

*Final Report  
Client: React, Inc.  
Study Number: CRL136502-1  
Page 3 of 10*

## FINAL REPORT

### REPEATED INSULT PATCH TEST

#### PURPOSE

The purpose of this study was to determine the dermal irritation and sensitization potential of a test material.

#### INVESTIGATIVE SITE

Clinical Research Laboratories, Inc.  
371 Hoes Lane  
Piscataway, New Jersey 08854

#### TEST MATERIAL

The following test material was provided by React, Inc. and was received by Clinical Research Laboratories, Inc. on December 17, 2002:

All Natural Cotton Powder - Unwashed Batch #2161

The test material was coded with the following CRL identification number:

CRL136502-1

The test material was applied to the patch as received.

#### STUDY DATES

This study was initiated on January 6, 2003 and was completed on February 14, 2003.



# Clinical Research Laboratories, Inc.

*Final Report  
Client: React, Inc.  
Study Number: CRL136502-1  
Page 4 of 10*

## PANEL SELECTION

Each subject was assigned a permanent CRL identification number. All subjects signed an Informed Consent Form in compliance with 21 CFR Part 50: "Protection of Human Subjects." All subjects completed a Subject Profile/Medical History Form provided by Clinical Research Laboratories, Inc. prior to the study (Subject Demographics - Appendix I).

No individuals were impaneled if they exhibited or had a history of acute or chronic dermatologic, medical, or physical conditions that could interfere with dermal scoring. No subject was using sympathomimetics, antihistamines, non-steroidal anti-inflammatory agents, or corticosteroids during the study period. No known pregnant or lactating women were impaneled in the study.

## TEST METHOD

Prior to the application of the patch, the test area was wiped with 70% isopropyl alcohol and allowed to dry. The test material, which was prepared as described in the Test Material section of the report, was applied under an occlusive patch\* to the upper back (between the scapulae) and was allowed to remain in direct skin contact for a period of 24 hours.

Patches were applied to the same site on Monday, Wednesday, and Friday for a total of 9 applications during the Induction Period. This schedule may have been modified to allow for missed visits or holidays. If a subject was unable to report on an assigned test date, the test material was applied on 2 consecutive days during the Induction Phase and/or a makeup day was added at the end of the Induction Phase.

The sites were graded by a CRL technician for dermal irritation and sensitization 24 hours after removal of the patches by the subjects on Tuesday and Thursday and 48 hours after removal of the patches on Saturday, unless the patching schedule was altered as described above.

\* Occlusive Strip with Flexcon® (TruMed Technologies Inc., Burnsville, Minnesota)  
The webril portion of the patch was moistened with water prior to test material application.



# Clinical Research Laboratories, Inc.

*Final Report  
Client: React, Inc.  
Study Number: CRL136502-1  
Page 5 of 10*

## TEST METHOD (Continued)

The sites were graded according to the following scoring system:

### Dermal Scores

- 0 No visible skin reaction
- ± Barely perceptible erythema (minimal)
- 1+ Mild erythema (diffuse)
- 2+ Well defined erythema
- 3+ Erythema and edema
- 4+ Erythema and edema with vesiculation

If a "2+" reaction or greater occurred, the test material was applied to an adjacent virgin site. If a "2+" reaction or greater occurred on the new site, the subject was not patched again during the Induction Phase but was challenged on the appropriate day of the study. At the discretion of the Study Director, patch sites with scores less than a "2+" may have been changed.

Following approximately a 2 week rest period, the challenge patches were applied to previously untreated test sites on the back. After 24 hours, the patches were removed by a CRL technician and the test sites were evaluated for dermal reactions. The test sites were re-evaluated at 48 and 72 hours. Subjects exhibiting reactions during the Challenge Phase of the study may have been asked to return for a 96 hour reading.



# Clinical Research Laboratories, Inc.

*Final Report  
Client: React, Inc.  
Study Number: CRL136502-1  
Page 6 of 10*

## **RESULTS**

This study was initiated with 56 subjects. Two subjects discontinued study participation for reasons unrelated to the test material. A total of 54 subjects completed the study.

Individual dermal scores recorded during the Induction and Challenge Phases appear in Table I.

## **CONCLUSION**

Based on the test population of 54 subjects and under the conditions of this study, the sample identified as All Natural Cotton Powder - Unwashed Batch #2161 did not demonstrate a potential for eliciting dermal irritation or sensitization.

## **RETENTION**

All of the original documents relating to this study will be retained by Clinical Research Laboratories, Inc. for a time period of at least 5 years or as otherwise required by law.

Test materials shall be archived by Clinical Research Laboratories, Inc. for a period no less than 6 months, unless otherwise instructed by Sponsor.



# Clinical Research Laboratories, Inc.

Final Report  
Client: React, Inc.  
Study Number: CRL136502-1  
Page 7 of 10

## Appendix I

### Subject Demographics

Subject Number	Subject Initials	CRL ID #	Age	Sex
1	RR	10112	43	F
2	BS	05985	38	F
3	SM	13629	34	M
4	IC	06700	47	F
5	DR	13607	53	F
6	KS	15214	46	F
7	GC	16144	50	F
8	CP	07181	68	F
9	DT	08793	47	F
10	EW	15765	59	F
11	CB	11578	51	F
12	HD	14182	69	M
13	JH	17384	52	M
14	MG	14013	33	F
15	AR	13392	62	F
16	TC	17273	37	F
17	JR	07770	48	F
18	CF	15788	44	F
19	PG	13984	42	F
20	KH	16635	34	F
21	MS	13316	34	F
22	AG	13983	64	F
23	JD	14135	34	F
24	AC	01439	49	F
25	MF	16400	21	F
26	HF	00706	68	F
27	CM	17394	50	M
28	LM	13745	58	F

Subject Number	Subject Initials	CRL ID #	Age	Sex
29	KM	09142	48	F
30	DM	15498	57	F
31	RK	15853	59	M
32	KF	17005	39	F
33	MS	09613	32	F
34	MS	09614	67	F
35	RS	12025	65	M
36	AF	07436	64	F
37	JH	16622	35	M
38	MB	16089	45	M
39	CP	15275	22	F
40	GD	04511	57	F
41	CE	12823	42	F
42	HP	16504	52	F
43	LP	16472	56	M
44	DM	13440	37	F
45	AT	06607	59	F
46	RT	06301	34	F
47	BA	16158	64	F
48	PM	01846	65	F
49	DA	04315	56	F
50	DM	06405	68	M
51	JM	10420	33	F
52	BC	01703	70	F
53	RF	10346	70	F
54	MP	14307	49	F
55	EP	12394	43	F
56	FM	12729	40	F



# Clinical Research Laboratories, Inc.

Final Report  
 Client: React, Inc.  
 Study Number: CRL136502-1  
 Page 8 of 10

**TABLE I**

**Tabulation of Individual Scores**

**Test Material:** All Natural Cotton Powder - Unwashed Batch #2161 (CRL136502-1)

**PATCH TEST CONDITION:** Test as received **PATCH TYPE:** Occlusive with moistened webril portion

Subject Number	Subject Initials	CRL ID #	Induction Scores									Challenge Scores				
			1	2	3	4	5	6	7	8	9	24 Hr	48 Hr	72 Hr		
1	RR	10112	0	0	0	0	0	0	0	0	0	0	0	0		
2	BS	05985	0	0	0	0	0	0	0	0	0	0	0	0		
3	SM	13629	0	0	0	0	0	0	0	0	0	0	0	0		
4	IC	06700	0	0	0	0	0	0	0	0	0	0	0	0		
5	DR	13607	0	0	0	0	0	0	0	0	0	0	0	0		
6	KS	15214	0	Discontinued Study												
7	GC	16144	0	0	0	0	0	0	0	0	0	0	0	0		
8	CP	07181	0	0	0	Discontinued Study										
9	DT	08793	0	0	0	0	0	0	0	0	0	0	0	0		
10	EW	15765	0	0	0	0	0	0	0	0	0	0	0	0		
11	CB	11578	0	0	0	0	0	0	0	0	0	0	0	0		
12	HD	14182	0	0	0	0	0	0	0	0	0	0	0	0		
13	JH	17384	0	0	0	0	0	0	0	0	0	0	0	0		
14	MG	14013	0	0	0	0	0	0	0	0	0	0	0	0		
15	AR	13392	0	0	0	0	0	0	0	0	0	0	0	0		
16	TC	17273	0	0	0	0	0	0	0	0	0	0	0	0		
17	JR	07770	0	0	0	0	0	0	0	0	0	0	0	0		
18	CF	15788	0	0	0	0	0	0	0	0	0	0	0	0		
19	PG	13984	0	0	0	0	0	0	0	0	0	0	0	0		
20	KH	16635	0	0	0	0	0	0	0c	0	0	0	0	0		
21	MS	13316	0	0	0	0	0	0	0	0	0	0	0	0		
22	AG	13983	0	0	0	0	0	0	0	0	0	0	0	0		
23	JD	14135	0	0	0	0	0	0	0	0	0	0	0	0		
24	AC	01439	0	0	0	0	0	0	0	0	0	0	0	0		
25	MF	16400	0	0	0	0	0	0	0	0	0	0	0	0		

c = Changed site for subject's comfort





# Clinical Research Laboratories, Inc.

Final Report  
 Client: React, Inc.  
 Study Number: CRL136502-1  
 Page 10 of 10

**TABLE I  
 (Continued)**

**Tabulation of Individual Scores**

**Test Material:** All Natural Cotton Powder - Unwashed Batch #2161 (CRL136502-1)

**PATCH TEST CONDITION:** Test as received **PATCH TYPE:** Occlusive with moistened webril portion

Subject Number	Subject Initials	CRL ID #	Induction Scores									Challenge Scores			
			1	2	3	4	5	6	7	8	9	24 Hr	48 Hr	72 Hr	
51	JM	10420	0	0	0	0	0	0	0	0	0	0	0	0	0
52	BC	01703	0	0	0	0c	0	0	0	0	0	0	0	0	0
53	RF	10346	0	0	0	0	0	0	0	0	0	0	0	0	0
54	MP	14307	0	0	0	0	0	0	0	0	0	0	0	0	0
55	EP	12394	0	0	0	0	0	0	0	0	0	0	0	0	0
56	FM	12729	0	0	0	0	0	0	0	0	0	0	0	0	0

c = Changed site due to tape reaction